(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 426 122 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
09.06.2004 Bulletin 2004/24

(51) Int Cl.[7]: **B08B 15/02**, F24F 3/16

(21) Application number: **03257430.3**

(22) Date of filing: **25.11.2003**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR
Designated Extension States:
AL LT LV MK

(30) Priority: **29.11.2002 GB 0227874**

(71) Applicant: **Extract Technology Limited**
Huddersfield HD2 1UR (GB)

(72) Inventors:
- **Horobin, Neal**
  Lundwood, Barnsley S71 5LF (GB)
- **Irfan, Mohammed**
  Fartown, Huddersfield, HD2 2PN (GB)

(74) Representative: **Stuttard, Garry Philip**
Urquhart-Dykes & Lord
Tower North Central
Merrion Way
Leeds LS2 8PA (GB)

(54) Isolator

(57) The present invention relates to a modular isolator comprising a plurality of conjoined modules, each module enclosing a quadrantal processing zone, and to the module *per se.*

EP 1 426 122 A1

Description

[0001] The present invention relates to a modular isolator comprising a plurality of conjoined modules, each module enclosing a quadrantal processing zone, and to the module *per se.*

[0002] Effective containment is essential for the safe and hygienic handling of a pharmaceutical, chemical or biological product. At each stage, handling must be controlled and managed to provide optimum protection for the operator and to maintain the integrity of the product. For example, current Good Manufacturing Practices (GMP) exercised within the pharmaceutical manufacturing industry demand good containment performance and acceptable operator exposure levels.

[0003] For handling a solid (eg powder) or liquid product of a sensitive or hazardous (eg toxic) nature in a processing zone, there are available a number of different types of containment assembly. In one such containment assembly, the air quality in the processing zone may be controlled using forced ventilation. One category of forced ventilation is "downflow" in which surrounding air is pushed downwardly to entrain airborne particles to a level below the processing zone (eg to a level below the operators particular breathing zone). For downflow containment, exhaust is usually carried out at low level relative to source of particles. This permits the downflow assembly to provide operator, product, and/or environmental protection for a range of powder and liquid handling applications. A downflow containment assembly may comprise an operator booth of sufficient size to admit the operator for the purposes of (for example) manipulating powder handling equipment (eg large powder kegs or bins weighing devices). One such assembly is disclosed in EP-A-1146293.

[0004] An alternative conventional containment assembly is a barrier isolator with gloved access to the processing zone in which a product and/or handling equipment may be manipulated. The use of a barrier system offers improvements in the handling of pharmaceutical products in circumstances where product protection and the maintenance of asepsis, and/or operator protection and the control of hazardous substances are critical requirements. A barrier isolator offers two fold protection, namely the use of glove ports to maintain a physical barrier between the product and the operator and a fan system to create air flow for removing airborne particles from the processing zone and into filters. In this manner, a barrier isolator may achieve high containment typically down to less than $10\mu g/m^3$ of contamination in the surrounding environment. One such isolator is disclosed in EP-A-1264668.

[0005] As a result of the economic and operational advantages of isolators, their use in hospital pharmacy in the UK is now widespread and over 400 are currently in use. They are designed and installed as individual units for aseptic preparation and dispensation of all forms of parenteral products and are commonly used in centralized cytotoxic reconstitution services, centralized IV additive services (CIVAS) and for the preparation of total parenteral nutrition (TPN) solutions. Isolators have several advantages over conventional clean rooms and laminar flow cabinets for aseptic preparation and dispensation of injectable formulations. Firstly they may be sited in an unclassified environment and still provide an acceptable level of sterility for aseptic operations. Secondly costs can be minimized because a minimum amount of costly protective clothing is needed. Furthermore, their operator and product protection efficiency is not affected by air turbulence around the cabinet since the processing zone is totally enclosed (whereas the protection properties of a vertical laminar flow drug safety cabinet for example can be significantly reduced by air turbulence across the front opening of the cabinet). Isolators cannot however be regarded as totally sealed units since there must be open access to the processing zone when materials are transferred in and out and the processing zone is continuously supplied with HEPA filtered air. Otherwise the processing zone of the isolator is sealed from its background environment in use.

[0006] Most isolators for aseptic processing use laminar (unidirectional) airflow, turbulent airflow or a combination of the two within the processing zone for the removal of airborne particles from the processing zone and into filters. It is generally accepted that the critical zone of the controlled surface should be equivalent to the EC grade A but the airflow in the critical zone need not be laminar flow. In the situation where a laminar flow system within the controlled critical zone is not provided, it is standard industry recommended practice for tests to be performed so as to confirm that only air complying with the requirement of EC Grade A is supplied to the critical zone. Furthermore, it is required that air should be effectively swept from the processing zone and standing vortices and stagnant areas should not exist.

[0007] Isolator technology is now widely used for the aseptic industrial processing of pharmaceuticals. Although the revenue and capital savings that hospitals have achieved may not be realized in industry, isolator technology can improve operator and product protection and increase sterility assurance. Production lines with integrated isolation technology are now being introduced into the pharmaceutical industry. Isolators are also used in microbiology departments for sterility testing which relies heavily on an effective aseptic technique.

[0008] Although one of the major advantage of these generally bespoke products is that they can be custom built at reasonable cost to comply with recommendations set out in current GMP guidelines, there is little or no consideration as to their aesthetic appearance and configuration. Indeed the majority of such products adopt a rather unsophisticated configuration (typically a box-like (eg square) configuration).

[0009] The present invention seeks to address certain disadvantages of a conventional containment assembly by providing an isolator whose modularity offers numer-

ous permutations of overall size and shape whilst beneficially assisting the operator to work at maximum efficiency. In particular, the present invention relates to a modular isolator comprising ergonomically designed modules which may be conjoined in various configurations to provide versatile and effective containment.

[0010] Thus viewed from one aspect the present invention provides a modular isolator comprising a plurality of conjoined modules, each module comprises a rigid body enclosing a processing zone and being adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone, wherein the processing zone is substantially quadrantal in the horizontal plane.

[0011] The rigid body may comprise a front face adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone and opposing, substantially perpendicular side faces convergent into a connecting rear face (or a common rear edge). Thus the quadrantal configuration of the processing zone is such that the side faces of the isolator are not perpendicular to the front face thereby advantageously optimising the ergonomic performance of the module (eg improving access to the side faces and to internal components or for rendering cleaning more straightforward and effective).

[0012] The rigid body may be manufactured to meet the requirements of the internal components that it houses. Typically the rigid body will be constructed from stainless steel and appropriate chambers provided for the internal components which it houses. Examples of internal components may include one or more filters or fan unit(s). For example, one or more fan units and valves may be housed in a rear chamber of the rigid body.

[0013] Such is the versatility of the modular isolator of the invention, an appropriate number of modules may be advantageously arranged to be used in isolation, against a flat wall of any length, in an interior or exterior comer, around a pillar (or similar elongate structure), against a stepped wall or wrapped around the walls of a room (eg wrapped around the three exterior walls of a square room). The modules may be abutted directly against the walls or indirectly via a single connecting module or more than one linearly conjoined connecting module. The modules may be conjoined directly or indirectly (eg spaced part by a single connecting module or more than one linearly conjoined connecting module).

[0014] In a preferred embodiment, the modular isolator comprises twin modules.

[0015] Particularly preferably the twin modules are conjoined directly and may be used in isolation or abutted (for example) directly against a flat wall. Alternatively the twin modules are conjoined directly and may be abutted (for example) indirectly against a flat wall via a single connecting module to create an island extending away from the wall (or more than one linearly conjoined connecting module where it is desired to extend the island further away from the wall).

[0016] Particularly preferably the twin modules are conjoined indirectly by a single connecting module (or more than one (eg two) linearly conjoined connecting modules) and may be used in isolation or abutted (for example) directly against a flat wall.

[0017] In a preferred embodiment, the modular isolator comprises three modules.

[0018] Particularly preferably the three modules are conjoined directly and may be used in isolation, wrapped around an elongate structure (such as a pillar) or abutted (for example) directly against an exterior corner wall.

[0019] It will be appreciated that more sophisticated arrangements of modules and connecting modules may be constructed in accordance with the invention to abut against (for example) stepped walls or the interior or exterior walls of a room. A plurality of conjoined modules (optionally with connecting modules) may be advantageously exploited in a stepwise process whereby each module facilitates a single step of the process.

[0020] The (or each) connecting module will be generally of a similar size to that of the modules of the invention to which it is connected. The (or each) connecting module is typically a conventional module which comprises a rigid body enclosing a processing zone and which may be adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone, wherein the processing zone is substantially quadrangular (*eg* square) in the horizontal plane. In all other respects, the preferred features of the (or each) connecting module are as defined herein for the module of the invention and may be chosen according to the requirements of the operator. Suitable connection means (such as rapid transfer ports) known to those skilled in the art may be deployed to connect the connecting module to a module in a contained manner.

[0021] The processing zone may be conveniently divided into a series of chambers which are tailored in terms of size, shape and position to meet the requirements of the use to which each module of the modular isolator is to be put. Typically an operating chamber is provided at or near to the height of the torso of an operator of average height (preferably in the seated position) and towards the front of the processing zone. The operating chamber may be bound by an internal rear wall (to the rear of which is a rear chamber). The sides of the operating chamber may be bound by side walls (which are preferably parallel).

[0022] In a preferred embodiment, at least an upper portion of the front face of each module is multi-faceted (*ie* provided with a plurality of exterior faces). Preferably at least one exterior face is adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone. Particularly preferably at least two exterior faces are adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone.

[0023] Preferably the upper portion of the front face of each module is bi-faceted (*ie* provided with two exterior faces). In practice, this provides the upper portion of the front face of each module essentially with a quarter of an octagonal profile and this angular disposition has been found to offer ergonomic advantages (in particular in optimising the operators reach).

[0024] Preferably the (or each) exterior face is inclined. This may serve to optimise ergonomic comfort of the operator and/or to assist airflow characteristics. Particularly preferably the internal rear wall bounding the operating chamber is inclined so as to be substantially parallel to the (or each) exterior face.

[0025] Preferably the (or each) exterior face is fully or partially transparent to provide visibility to the processing zone (*eg* to the operating chamber).

[0026] Typically the exterior face adaptable to permit an operator outside the processing zone to reach into the processing zone is a barrier means. The barrier means may be detachable (*eg* removable or openable) by suitable means to provide unhindered access to the processing zone if desired. For example, the barrier means may be hinged at one or more locations. The barrier means may be sealed against the rigid body using conventional sealing methods to provide product and operator protection and maintain aseptic conditions. The (or each) seal may be fitted to the barrier means or rigid body in such a way as to provide maximum sealing of the barrier to the isolator in all conditions. For example, the seal may be housed in the barrier means and act against a suitable sealing platform (*eg* on the rigid body). The seal may be fitted to the barrier means by (for example) a groove running along the external circumference of the barrier means and may be pneumatically or hydraulically controlled using a suitable mechanism to provide optimum sealing force and pressure against one or more rigid support structures on the rigid body. Pipe work or supporting connections to the seal can be channelled to enhance the aesthetics of the modular isolator (*eg* a pneumatic seal hose could be channelled through the hinge mechanism(s)).

[0027] Preferably the (or each) exterior face comprises one or more apertures (*eg* substantially oval apertures) each fitted with a flexible portion in the shape of a glove (or capable of being deformed into the shaped of a glove) which permits an operator outside the processing zone to reach into the processing zone (whilst providing physical protection from the processing zone and any biological, chemical or other substances that may be present). Typically the (or each) exterior face comprises two flexible portions in the shape of a glove (or capable of being deformed into the shape of a glove) sealed conventionally for operator protection during (for example) cleaning.

[0028] In a preferred embodiment, the (or each) flexible portion in the shape of a glove (or capable of being deformed into the shape of a glove) comprises a flexible sleeve terminating in a gloved end (*eg* a gauntlet). Preferably in use the flexible sleeve extends from the exterior face (*eg* the barrier means) to beyond the operators elbow (to optimise manoeuvrability). The flexible sleeve may be composed of natural or synthetic rubber or polyurethane. The gloved end is typically (but not necessarily) composed of less flexible material than the flexible sleeve. For example, the gloved end may be composed of thicker polyurethane than that of the flexible sleeve (or alternatively of thicker PVC, rubber or other material).

[0029] The gloved end may be integral with the flexible sleeve or attached to the flexible sleeve in any conventional manner. Preferably (but not necessarily) the joint between the gloved end and the flexible sleeve comprises an internal strengthening ring to which the ends of the gloved end and the flexible sleeve are attached and/or secured. For example, the ends of the gloved end and the flexible sleeve may be secured to the internal strengthening ring by an elastic band or the like.

[0030] The end of the (or each) flexible portion in the shape of a glove (*eg* the flexible sleeve) may comprise a bead or rolled edge for fitting to the exterior face (*eg* the barrier means). For example, the bead or rolled edge may be stretchably mounted on to a face ring (*eg* a groove of the face ring) on the exterior face (*eg* barrier means) to produce an airtight joint. The joint may be strengthened by a strengthening ring (*eg* an o-ring) inserted into a second groove on the face ring. Suitable glove sealing arrangements are disclosed in EP-A-1265257.

[0031] Typically the position and orientation of the (or each) flexible portion in the shape of a glove may be tailored to suit the particular operation to be conducted in the processing zone. For example, the (or each) flexible portion in the shape of a glove may be right hand or left hand oriented as desired.

[0032] In an embodiment of the invention, the rigid body further comprises: one or more transfer ports to permit contained transfer from the processing zone to a remote location. Preferably the (or each) transfer port is a tubular transfer port. The remote location may be a module of the invention, a connecting module, a powder bin, containment assembly, etc.

[0033] A first transfer port may be incorporated into a first side face. A second transfer port may be incorporated into a second side face. The quadrantal configuration of the processing zone is such that any transfer port in the side face of the isolator is not perpendicular to the front face adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone thereby optimising the ergonomic performance of the module (*eg* optimising operator access to the transfer port).

[0034] The processing zone may be provided with a work platform (preferably a perforated work platform). Such a work platform is typically in the operating chamber and may be equipped with means for determining

its horizontal level (*eg* by using a spirit level type device) and may be adjustable by (for example) adjustable screw fixings, pneumatic or hydraulic levelling mechanisms. Normally the work platform is located at or near to the waist height of a typical operator. Beneath the working platform is a lower chamber.

[0035] The modular isolator may be adapted to provide non-circulatory airflow in the processing zone. For example, air exhausted from the processing zone may be ducted to atmosphere or to a remote location (*eg* a fan/filter stack).

[0036] In a preferred embodiment, the modular isolator further comprises:

a rigid body defining a first and second chamber;
recirculating means for inducing re-circulatory airflow in the processing zone, wherein the first chamber is adapted with one or more outlets to receive the airflow from the processing zone and
the second chamber is adapted with one or more inlets to transmit the airflow to the processing zone.

[0037] Preferably the first chamber is the lower chamber and the second chamber is the upper chamber. For example, the or each outlet may be incorporated in (but not necessarily parallel to) a lower wall bounding the lower chamber (beneath the working platform) and the or each inlet may be incorporated above (but not necessarily perpendicular to) the working platform. The or each outlet is generally fitted with an outlet filter and the or each inlet is generally fitted with an inlet filter. A filter may be fitted to the rigid body using conventional mechanical and/or adhesive means (*eg* using silicone gel and knife-edge sealing technology in a suitable configuration). Typically the filter is a conventional HEPA filter.

[0038] Preferably the modular isolator of the invention is adapted so that air flows downwardly in an undisturbed, non-turbulent manner in the processing zone at a pre-determined velocity.

[0039] Preferably the rigid body is adapted to attain laminar flow (eg perfect laminar flow (PLF) of air in the processing zone). For this purpose, the inlet is preferably fitted with PLF material (*eg* a PLF screen) through which the air flows to the processing zone. For example, the inlet may be fitted with a tensioned monofilament woven screen providing uniform air flow over its entire area. The screen may be fitted to the inlet in a conventional manner (*eg* using standard adhesives such as urethane adhesives). The PLF screen may be a perimeter frame (*eg* of welded steel) which is typically cross braced (*eg* with hollow tubes) to resist the tensile forces of a monofilament textile screen stretched and fixed to the perimeter of the frame. The monofilament textile screen retards the passage of air so that it is forced to pass through it with an even velocity distribution (the down flow velocity) which suppresses the rise of particles in the processing zone. In microbiological processing (and similar) applications, it is generally necessary to include a HEPA filter upstream of the PLF screen to reduce the relevant risk of environmental contamination.

[0040] In a preferred embodiment, the inlet filter itself provides laminar flow air to the processing zone. For this purpose, the inlet filter (*eg* HEPA inlet filter) may be a construction with appropriate rigidity and structure and a suitable shape to provide a similar function to a PLF screen. The inlet filter retards the passage of air so that it is forced to pass through it with an even velocity distribution (the down flow velocity) which suppresses the rise of particles in the processing zone.

[0041] In an embodiment of the modular isolator of the invention, the upper chamber defines a plenum capable of transmitting the airflow downwardly into the processing zone. Preferably the upper chamber is adapted to contribute to laminar flow (*eg* PLF). The upper chamber may take the form of a profiled canopy capable of providing a smooth and uninterrupted airflow into the inlet fitted with a PLF screen and/or the inlet filter (*eg* a HEPA filter).

[0042] The means for inducing airflow may comprise any conventional fan unit *eg* a fan unit driven by a flange mounted inverter controlled motor which ensures smooth drive via a flexible coupling. The means for inducing air flow may be located in the rear chamber. The fan unit may be placed downstream from a filter ensuring that it only receives clean filtered air. The fan unit may be a double scroll double inlet type fan optionally but preferably with automatic constant volume control which compensates for filter congestion and with set back duty for when the modular isolator is operated in isolator mode. The fan unit may be seated on highly compressed antivibration mounts to ensure that no vibration is passed onto adjacent parts of the body. The fan may be programmable to switch between any number of different volumetric flow rates for use in various operational modes and process requirements.

[0043] The rigid body may comprise a bleed port (*eg* suitably dusted from the airflow circuit) which is open for use in standard isolator mode but which may be closed (if desired) to allow the discharge of air for the effective operation of the modular isolator. The bleed port may (if desired) be substituted by a filter (*eg* a HEPA filter) to further minimize the risk of environmental contamination.

[0044] The modular isolator may further comprise one or more vents to ensure that the temperature of the air in the motor section does not rise to unacceptable levels though the action of the motor on the fan (if the fan is not self cooling). The venting of the motor chamber may be aided by an additional cooling or air-circulating fan.

[0045] In a preferred embodiment, the modular isolator is adapted to accommodate negative and positive pressure (*eg* by operating valves for inlet and outlet airflow in relation to filter position in the airflow circuit).

[0046] Laminar flow light fittings or luminaries may be mounted in the upper chamber or operating chamber of

the rigid body. The light fittings may be removable from the rigid body and replaced (for example) with ultra-violet light fittings in the original setting whilst the module is in normal operational mode. The light fittings may be removable from a front or top face of the module. The lighting pod may be removable for changing damaged light fittings or changing to (for example) ultra-violet lights for certain process applications before, during or after operation of the isolator. The lighting pod is a tube or shaped form constructed from a clear material (*eg* plastic acrylic or glass) suitably sealed to the rigid body. Within the lighting pod is a smaller item that includes the lights, starter capacitor and other required wiring and components such as a plug or twist fit connector. The lighting pod is capped off by a lid and secured in a closed position on the front face of the isolator. Any number of light fittings my be used to obtain the relevant amount of light and light distribution in the processing zone. The removable section of the light fitting may adopt a "Y" or "X" shape where the uppermost section of the Y or X includes the lighting components and other sections contain tube lights. The surface upon which the lights are mounted may be of a reflective material providing a greater distribution and diffusion of light.

[0047] The modular isolator may be mobile. The exterior of the rigid body may be fitted with a plurality of mobility means for rendering the modular isolator mobile (*eg* castors). Preferably each means for rendering the modular isolator mobile is mounted on the end of an elongate member (*eg* a steel frame leg). Typically the modular isolator comprises a plurality of castors mounted at suitable locations at the ends or comers of the base of the rigid body for effective mobility.

[0048] Suitable shelving or other storage means may be provided in the processing zone (*eg* in the operating chamber).

[0049] Typically the modular isolator is configured to permit the operator to reach into the processing zone (*eg* to conduct the process or processes for which the isolator is designed) from a seating position. Typically the modular isolator is adapted to fit through industry standard doors (*eg* through a standard door height (*eg* 1950mm)).

[0050] The modulator isolator may further comprise: a housing for mechanical and electrical and/or electronic components to facilitate the operation of the isolator and/or required airflow characteristics.

[0051] Preferably the modular isolator of the invention may be used to conduct processes such as transfer of hazardous products, sterility testing, processing pharmaceutical, biotechnology and/or medical products, laboratory testing, packaging and other processing applications within the pharmaceutical, biotechnology and related fields. The versatility of the modular isolator is such that conjoined modules may be used to carry out complimentary steps of a process *eg* sterility testing in a first module and packaging in a second, conjoined module.

[0052] The configuration of each module *per se* is such that a single one is usable in isolation or in confined or restrictive locations (*eg* around an interior comer) with optimum ergonomic performance. Thus the module *per se* is independently patentable.

[0053] Viewed from a further aspect the present invention provides a module as hereinbefore defined.

[0054] The module may be used in isolation or abutted (for example) directly against an interior corner wall. Alternatively the module may be conjoined with a single connecting module (or more than one linearly conjoined connecting modules) and use in isolation or abutted against an interior corner wall.

[0055] The invention will now be described in a non-limitative sense with reference to the accompanying Figures in which:

Figure 1 illustrates a perspective view of an embodiment of the module of the invention;
Figure 2 illustrates a plan elevational view of the embodiment of the module of the invention;
Figure 3 illustrates a front elevational view of the embodiment of the module of the invention;
Figure 4 illustrates a side elevational view of the embodiment of the module of the invention;
Figure 5 illustrates a sectional view (along AA of Figure 3) of the embodiment of the module of the invention;
Figure 6 illustrates a simplified sectional view of the embodiment of the module of the invention; and
Figure 7 illustrates a plan elevational view of various embodiments of the modular isolator of the invention.

[0056] Figures 1 to 6 illustrate various views of an embodiment of the module of the invention 1 which comprises a rigid body 100. The upper portion of the front face 1a of the rigid body 100 is essentially bifaceted (*ie* with first and second exterior faces 1b and 1c) so that its external surface adopts a quarter octagonal configuration defining internally a processing zone 2 which is substantially quadrantal.

[0057] Two transparent clear plastic (or glass) barrier doors 3a and 3b are attached respectively to the first and second exterior faces 1a and 1b. Each door 3a and 3b is provided with a single or double hinge 4 for opening in a horizontal plane (but it will be appreciated that the hinge could equally be provided on an upper edge for opening in a vertical plane). The doors 3a and 3b are provided with a door locking mechanism 200 comprising a rotating rod 200a extending into a specified fixing and locking point 200b. A seal (not shown) runs around the outer circumference of the door 3a, 3b acting against the door frame along the direction of the doors height and width but not the doors thickness and locks itself into a groove on the doorframe ensuring a good seal and acting as a door locking mechanism. This ensures that there are little or no stresses created in the door 3a,

3b so that a separate physical locking mechanism (such as a lever) is not required. A seal hose connection 5 and hydraulic/pneumatic components serve to inflate and deflate the seal as required.

[0058] Three part injection moulded glove ports 6 are provided for the safe installation and changing of gloves. Connections 7 in the lower front part of the rigid body 100 are routed internally to relevant ducting points to provide vaporized hydrogen peroxide for decontamination and sterilization of the processing zone. A control section 8 houses user or maintenance interface components and is closed by door 20. A process equipment bay 9 houses specified equipment to facilitate desired operations. Process equipment may be located and installed in a process equipment bay 10 specifically catering for standard components such as a Millipore integral sterility testing system. A touch panel user interface 11 includes digital and analogue feedback on isolator performance and processes, alongside a full control interface for processes and applications.

[0059] Attached to the rear of the rigid body 100 is a motor section cover 15 covering *inter alia* air flow dynamics control valves and piping 25. An internal wall 39 and parallel side walls define an operating chamber 16 with provision for shelving and ensure PLF conditions to a pre-determined pressure and flow rate. In the operating chamber 16 is a perforated work platform 32 beneath which a lower chamber 33 defines a plenum. The operating chamber 14 is also fitted with a removable lighting pod 28 encapsulated by a fully sealed clear plastic or glass light pod bay 30 and being fully sealed to enable interchange of light fittings during product processing without compromising sterility. The lighting pod 28 may be fitted with non-standard light fittings (such as UV fittings) before, during or after a process. A lighting pod power connector 38 is provided with a twist or plug action fitting. A front handle 29 is provided for light pod removal using a twist locking mechanism.

[0060] Side panels 13 may be provided with rapid transfer ports (not shown) or other user specified equipment as required. Five castors 12 are located on the base of the rigid body 100 for transportability.

[0061] An upper chamber 14 defines a plenum 26 (front section) and 37 (rear section) encasing an inlet filter 17 having dual functionality as a PLF screen and HEPA filtration unit. Access ports (not shown) may be located in the upper chamber 14, plenum (front section) 26 and/or plenum (rear section) 37. A gel sealing section 18 is provided for the inlet filter 17 using knife edge gel seal technology.

[0062] Airflow is controlled by a high power dual scroll centrifugal fan 22 with integral motor mounted on a motor mounting 23 and supply air valves 21 downstream thereof. Return filter bays 24 in the lower chamber 33 encapsulate a return filter 42 (a HEPA filtration panel) with a knife edge seal 43 in which gel is applied to the return filter 42 itself and a handle 31 for sealing and locking the return filter 42. The handle 31 extends from a plate 31a covering the gap between the return filter 42 and the return filter bays 24 and a wedge section 34 on the plate 31a is positioned against locking lugs 35 to seal and clamp the return filter 42 in place.

[0063] Figure 7 illustrates schematically various embodiments of a modular isolator of the invention in which modules as described with reference to Figures 1-6 have been arranged in various configurations and locations:

(1) A single module 45 in isolation and in an internal comer of a building or processing facility with product input P and output Q located behind walls W1 thereby ensuring separation of sterile environments.

(2) Twin modules 45a, 45b in isolation, against a flat wall W2 of a building or processing facility with product input P and output Q locations ensuring separation of sterile environments and against a flat wall W6 with two pairs of linearly conjoined connecting modules 44 with product input P and output Q locations behind wall W6 thereby ensuring separation of sterile environments. The overall assembly protrudes out into open space like an island.

(3) A single module 45c in isolation with two linearly conjoined connecting modules 44 with product input P and output Q locations ensuring separation of sterile environments or against an internal corner of a building or processing facility with product input P and output Q located behind walls W5 thereby ensuring separation of sterile environments.

(4) Two spaced apart modules 45d, 45e against a flat wall W3 of a building or processing facility conjoined by two linear connecting modules 44 with product input P and output Q locations behind wall W3 thereby ensuring separation of sterile environments.

(5) Three modules 45f, 45g, 45h in isolation or against an external comer of a building or processing facility with product input P and output Q locations behind walls W4 thereby ensuring separation of sterile environments. This arrangement may equally be arranged around a pillar (not shown).

(6) Two spaced apart modules 45k and 45l against a stepped wall W7 of a building or processing facility with one pair of connecting modules 44a and a single connection unit 44b and with product input P and output Q locations highlighted behind wall W7 ensuring separation of sterile environments into (for example) different laboratories.

(7) Two pairs of twin modules 45m, 45n and 45p, 45q wrapped around the walls W8 of a room (eg of

a building or processing facility) with a pair of linearly conjoined connecting modules 44 and with product input P and output Q locations highlighted behind the walls W8 ensuring separation of sterile environments.

Claims

1. A modular isolator comprising a plurality of conjoined modules, each module comprising:
a rigid body enclosing a processing zone and being adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone, wherein the processing zone is substantially quadrantal in the horizontal plane.

2. A modular isolator as claimed in claim 1 wherein at least one exterior face is adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone.

3. A modular isolator as claimed in any preceding claim wherein at least two exterior faces are adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone.

4. A modular isolator as claimed in claim 2 or 3 wherein the or each exterior face is inclined.

5. A modular isolator as claimed in claim 2, 3 or 4 wherein the internal rear wall bounding the operating chamber is inclined so as to be substantially parallel to the or each exterior face.

6. A modular isolator as claimed in any of claims 2 to 5 wherein the or each exterior face comprises one or more apertures each fitted with a flexible portion in the shape of a glove or capable of being deformed into the shaped of a glove which permits an operator outside the processing zone to reach into the processing zone.

7. A modular isolator as claimed in any preceding claim wherein the rigid body comprises:
a front face adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone and opposing, substantially perpendicular side faces are convergent into a connecting rear face or a common rear edge.

8. A modular isolator as claimed in any preceding claim comprising twin modules.

9. A modular isolator as claimed in claim 8 wherein the twin modules are conjoined directly.

10. A modular isolator as claimed in claim 8 wherein the twin modules are conjoined indirectly by a single connecting module or more than one linearly conjoined connecting modules.

11. A modular isolator as claimed in any of claims 1 to 7 comprising three modules wherein the three modules are conjoined directly.

12. A modular isolator as claimed in claim 10 wherein the or each connecting module comprises a rigid body enclosing a processing zone and which is adapted or adaptable to permit an operator outside the processing zone to reach into the processing zone, wherein the processing zone is substantially quadrangular in the horizontal plane.

13. A modular isolator as claimed in any preceding claim wherein at least an upper portion of the front face of each module is multi-faceted.

14. A modular isolator as claimed in any preceding claim wherein the upper portion of the front face of each module is bi-faceted.

15. A module as defined in any preceding claim.

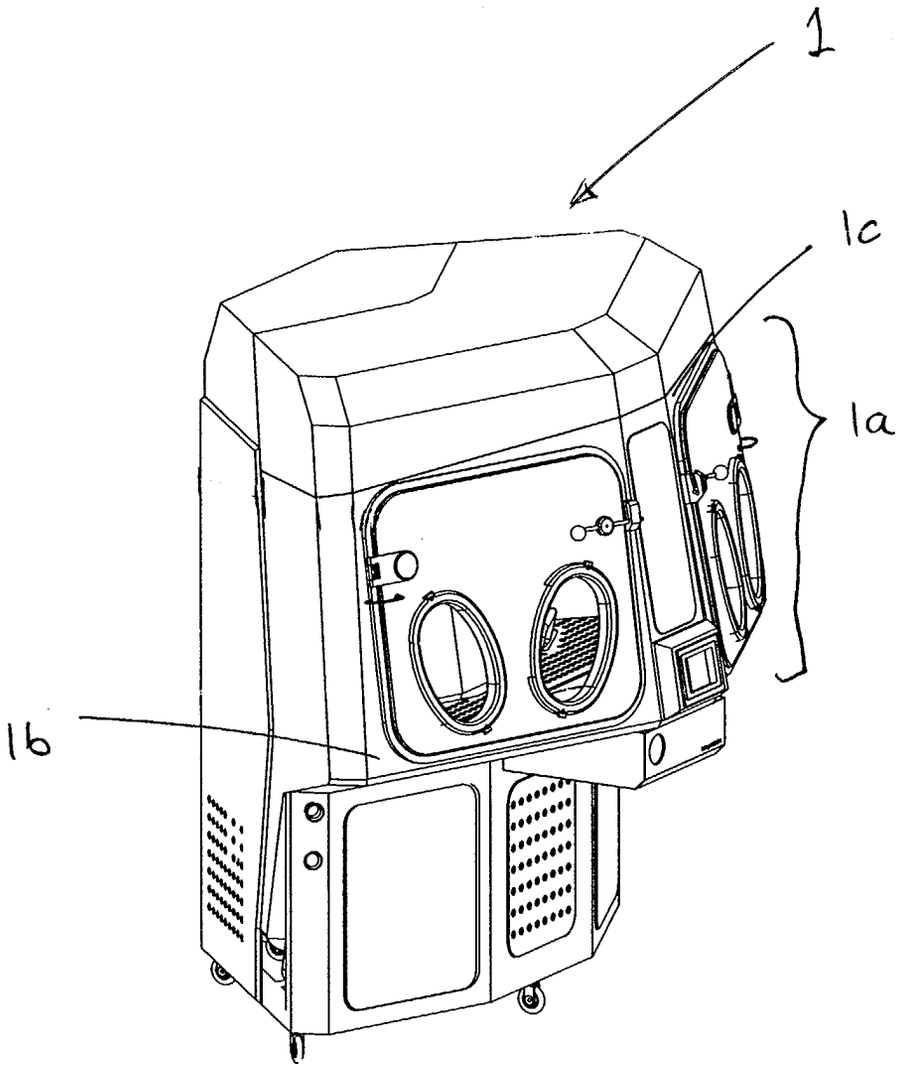


figure 1

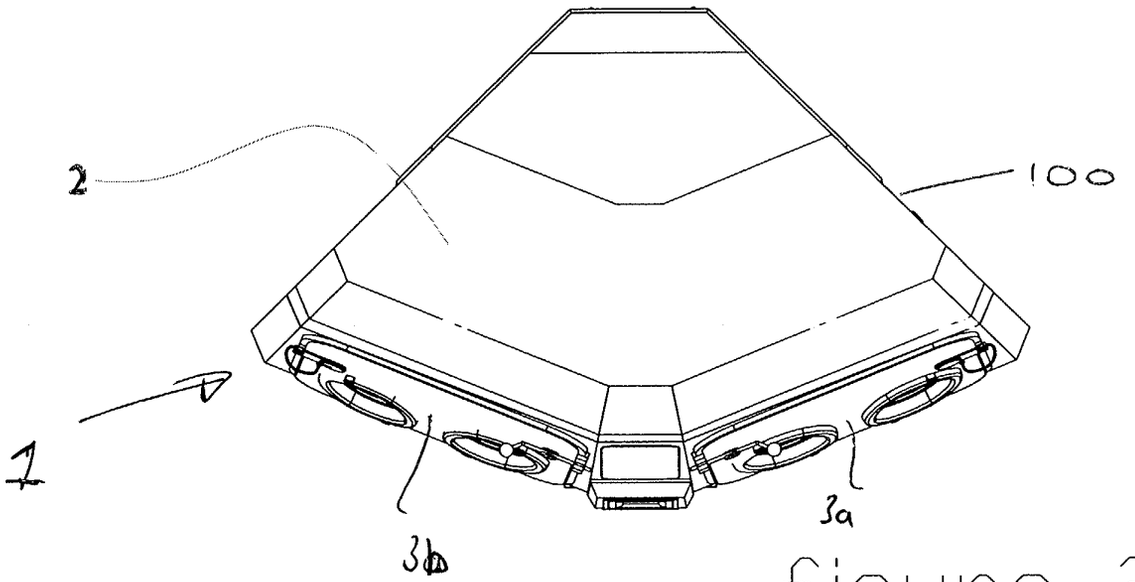


figure 2

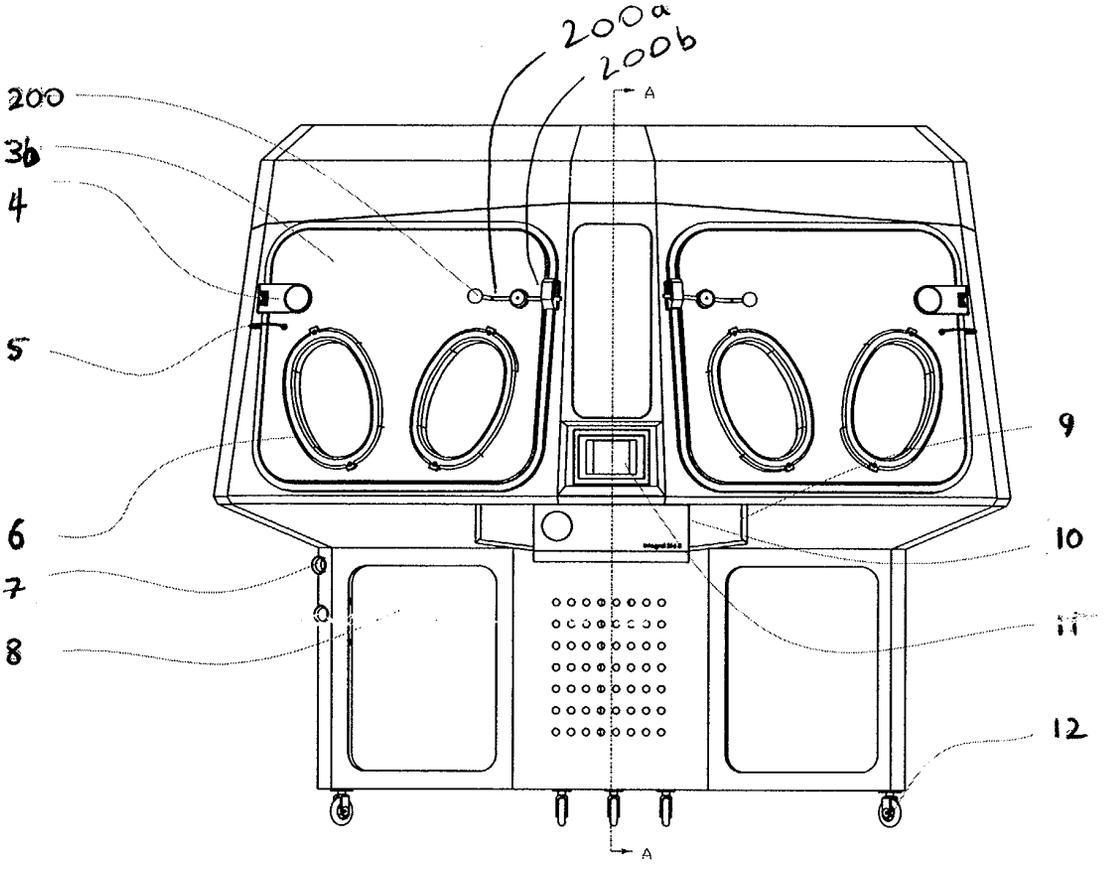


figure 3

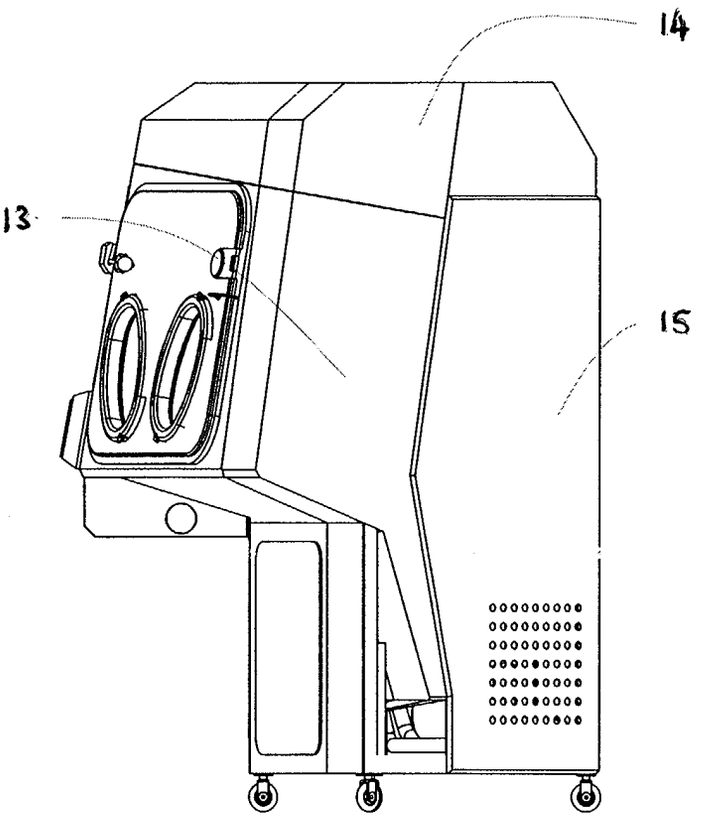
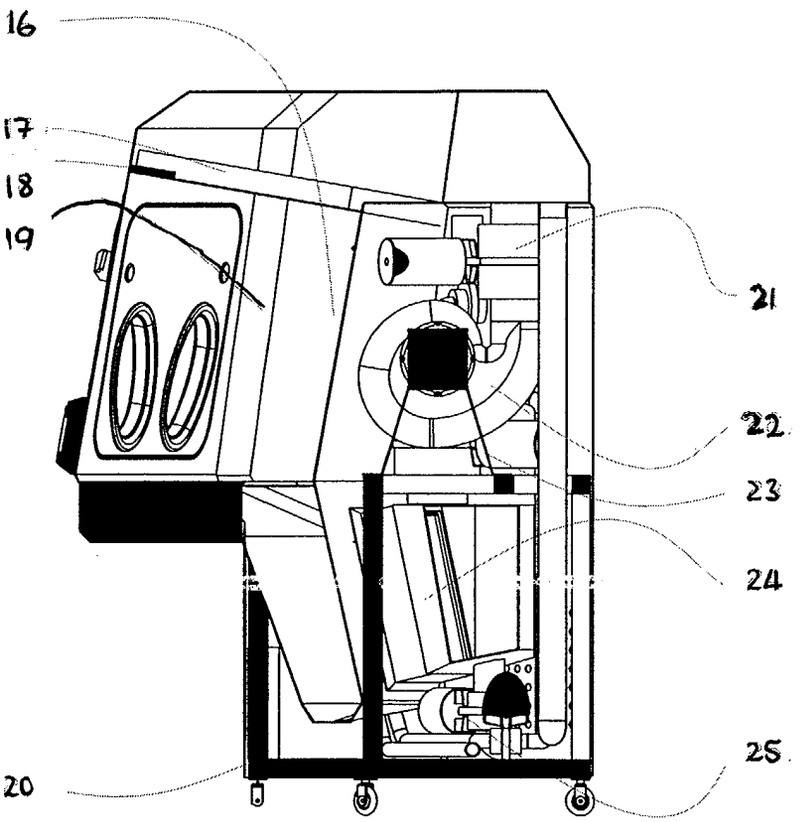


figure 4



SECTION A-A

figure 5

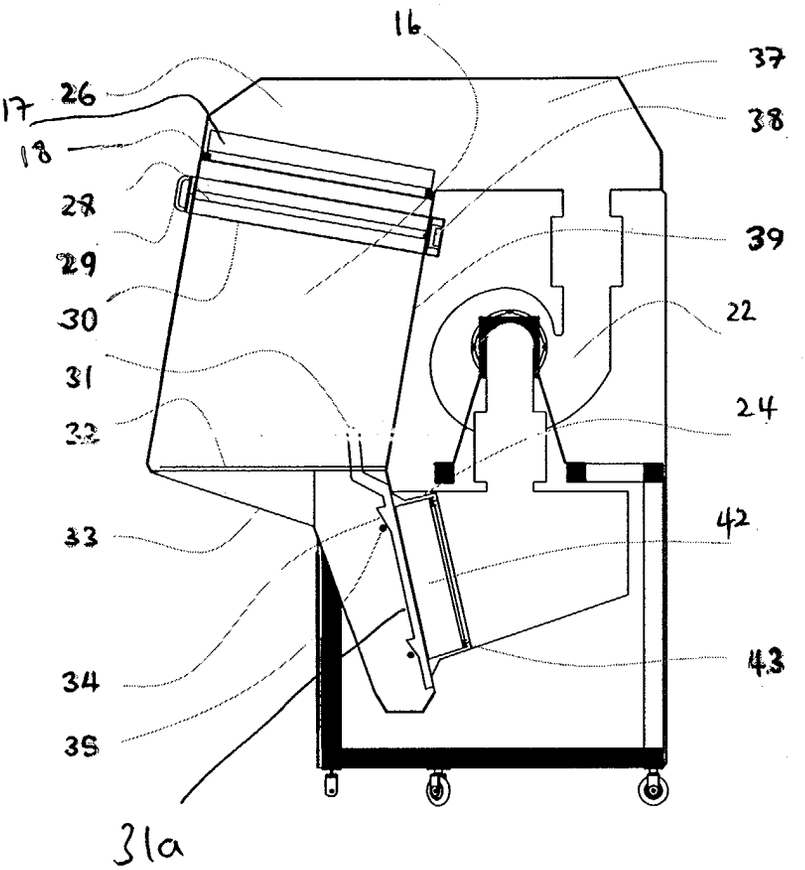


figure 6

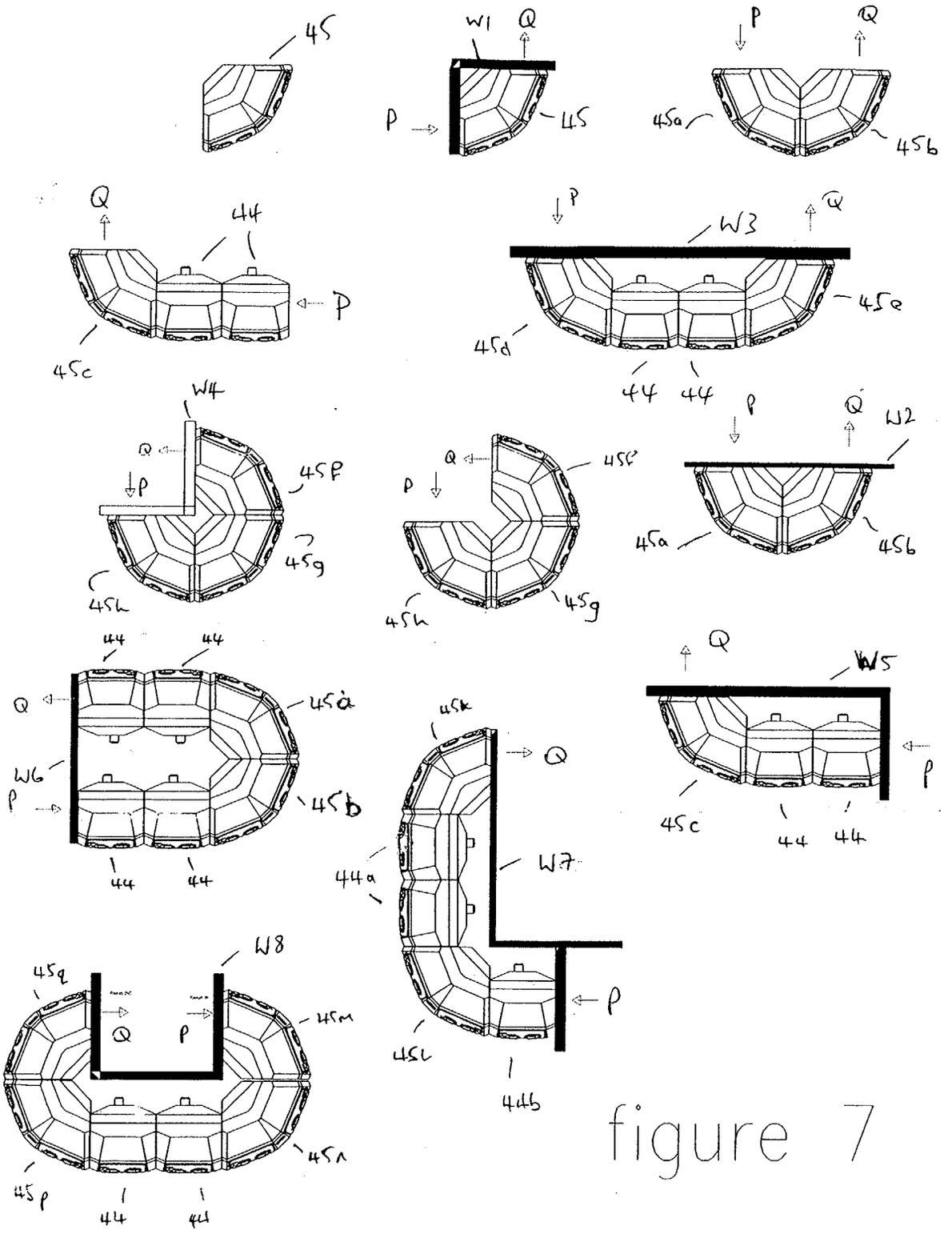

45
W1
Q
P
45
P
Q
45a
45b
Q
44
P
45c
P
W3
Q
45e
45d
44
44
W4
Q
P
45f
45g
45h
Q
45f
P
45g
45h
P
Q
W2
45a
45b
44
44
Q
45k
Q
W7
44a
P
45l
44b
W5
Q
P
45c
44
44
W8
45q
Q
P
45m
45n
45p
44
44

figure 7

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 03 25 7430

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	US 5 219 215 A (AKAGAWA MINORU ET AL) 15 June 1993 (1993-06-15) * the whole document * ---	1-14	B08B15/02 F24F3/16
A	EP 0 604 925 A (METALL & PLASTIC GMBH) 6 July 1994 (1994-07-06) * abstract * ---	1-14	
A	US 4 832 753 A (PLATT CHRISTOPHER W ET AL) 23 May 1989 (1989-05-23) * abstract * ---	1-14	
A	US 5 487 768 A (EGLINTON ROBERT B ET AL) 30 January 1996 (1996-01-30) * abstract * ---	1-14	
A	PATENT ABSTRACTS OF JAPAN vol. 2000, no. 06, 22 September 2000 (2000-09-22) & JP 2000 085961 A (SHIN MEIWA IND CO LTD), 28 March 2000 (2000-03-28) * abstract * -----	1-14	

TECHNICAL FIELDS SEARCHED (Int.Cl.7)

B08B
F24F
B25H
B25J
G21F
B01L

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
MUNICH	25 February 2004	Valenza, D

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

European Patent Office

INCOMPLETE SEARCH SHEET C

Application Number
EP 03 25 7430

Claim(s) searched completely:
1-14

Claim(s) not searched:
15

Reason for the limitation of the search:

The formulation of claim 15 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claim unclear (Art. 84 EPC). Therefore the present application fails to comply with the clarity and conciseness requirements of Article 84 EPC (see also Rule 29(5) EPC) to such an extent that a meaningful search is impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear (and concise), namely claims 1-14.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 03 25 7430

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

25-02-2004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5219215 A	15-06-1993	JP 5157302 A	22-06-1993
EP 0604925 A	06-07-1994	DE 9217873 U1	24-06-1993
		DE 4344439 A1	17-11-1994
		DE 9321602 U1	30-11-2000
		DE 59304196 D1	21-11-1996
		EP 0604925 A1	06-07-1994
		US 5522767 A	04-06-1996
US 4832753 A	23-05-1989	US 4936922 A	26-06-1990
US 5487768 A	30-01-1996	WO 9711792 A1	03-04-1997
		AU 3829295 A	17-04-1997
		EP 0879099 A1	25-11-1998
JP 2000085961 A	28-03-2000	NONE	

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82